Kontron Medical S.A.S 510(k) Submission Sigma 110/330 Ultrasound Systems

510(k) Summary

June 5, 2000

(1) Submitter Information

Name: Kontron Medical S.A.S. Address: 52, rue Pierre Curie

78370 Plaisir

France

Manufacturing Address: Same Telephone: +33 1 30 57 66 00

Contact Person: Dr. George Myers (Official Correspondent)

Medsys Inc. 377 Rt. 17 S Hasbrouck Heights, NJ 07604 201-727-1703 Fax 201-727-1708

Date Prepared: June 5, 2000

(2) Name of Device:

Trade Name: Sigma 110/330 Diagnostic Ultrasound System Common Name: Diagnostic Ultrasound System and Probes

Classification Name: (a) System, Imaging, Pulsed echo, Ultrasonic 90 IYO

(b)Transducer, Ultrasonic, Diagnostic, 90 ITX

(3) Equivalent Legally-Marketed Devices:

GE Logiq 500, K953752

The technological characteristics of the predicate device are the same as those of the ew device.

(4) Description

The "Sigma 110 / 330" is a small, modular ultrasound instrument intended to perform the following diagnostic ultrasound investigations: Imaging (B-mode), Time motion (TM-mode), Pulsed wave Doppler (PW Doppler), Continuous wave Doppler (CW Doppler) and Color Flow Mapping (CFM). CFM is only possible in conjunction with electronically scanned transducers on the Sigma 330 systems.

This submission also includes the transducers necessary for these procedures.

(5) Intended Use

Diagnostic ultrasound investigations including: Imaging (B-mode), Time motion (TM-mode), Pulsed wave Doppler (PW Doppler), Continuous wave Doppler (CW Doppler) and Color Flow Mapping (CFM).

(6) Performance Data

(a) Non-clinical tests

The Sigma 110/330 devices have successfully passed IEC 601-1 (electrical safety) and IEC 601-1-2 (electromagnetic compatibility), biocompatibility tests for patient contact materials, and accuracy tests for all biocompatibility modes, as well as software validation tests.

(b) Clinical Tests

Since the Sigma 110/330 uses the same technology and principles as existing devices, clinical tests are not required. However, a clinical demonstration showing the images obtainable on the different modes is also presented.

(c) Conclusion

The Sigma 110/330 Ultrasound sysytem with the associated tansducers is equivalent in safety and efficacy to the legally-marketed predicate device.



AUG 8 2000

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Kontron Medical Systems S.A.S. c/o CITECH Mr. Robert Mosenkis President Medical Device Testing and Consulting 5200 Butler Pike Plymouth Meeting, Pennsylvania 19462-1298

Re: K002239

Sigma 110/330 Diagnostic Ultrasound System

Regulatory Class: II

21 CFR §892.1550/Procode: 90 IYN 21 CFR §892.1560/Procode: 90 IYO

Dated: July 21, 2000 Received: July 24, 2000

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the transducers listed below intended for use with the Sigma 110/330 Diagnostic Ultrasound System as described in your premarket notification.

3.5 MHz CV	5.0 MHz CUR	5.0 MHz LIN
7.5 MHz LV		
	7.5 MHz LVS	7.5 MHz LVD
6.5 MHz VMC	6.5 MHz EV	6.5 MHz MR
3.5 MHz GP	3.5 MHz GPD	3.5 MHz GL
5.0 MHz GP	5.0 MHz GL	7.5 MHz GP
7.5 MHz GL	14 MHz PV	2 MHz TCD
2 MHz PEN	4 MHz PEN	8 MHz PEN

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further

Page 2 – Mr. Robert Mosenkis

announcements concerning your device in the <u>Federal Register</u>. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Mr. Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.

Captain, USPHS

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosures

1.3 Indication for use

Diagnostic Ultrasound Indications for Use Form

System: Sigma 110 / 330

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation													
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)				
Ophthalmic														
Fetal		N	N	N	N	N	N							
Abdominal		N	N	N	N	N	N							
Intraoperative (specify)									t akt i sa	*** 1 4.4				
Intraoperative Neurological														
Pediatric		N	N	N	N	N	N							
Small organs (specify)		N	N	N	N	N	, N		0 - 52 - 03	- 18 Th 12 This 240				
Neonatal Cephalic		N	N	N	N	N ,	N							
Adult Cephalic		N	N	N	N	N	N	125 1 1 1286	a just sa dijanja	1 - 15 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				
Cardiac		N	N	N	N				, i					
Transesophageal								r nove sance	+ 11 10 10 000 000	in managed and a company				
Transrectal		N	N	N		N	N		,					
Transvaginal		N	N	N		N	N	V. Asia	To the first age of	er en la caractería de esta en la compansa de la c La compansa de la co				
Transurethral														
Intravascular										20 19k				
Peripheral Vascular		N	N	N	N	N .	. N							
Laparascopic		1			***************************************									
Musculo-skeletal Conventional		N	N	N	N	N	N	To enterent year singer!		ja Svinstauena – kinnin sua				
Musculo-skeletal Superficial		N	N	N	N	N	N		1.0					
Other (specify)														

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional

Comments:

......Color Doppler & Amplitude Doppler only on Sigma 330 Systems

Small organs: Thyroid, Breast, Testicle

Concurrence of CDRH, Office of Devices Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Section B

Prescription Use (Per 21 CFR 801.109)

and Radiological Devices

System: Sigma 110 / 330

Transducer: 3.5 MHz CV

]					Mode of O	peration			
Clinical Application	Α	В	М	PWD	cwo	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		•	
Abdominal		N	N	N		N	N			
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N			
Small organs (specify)									েজ	
Neonatal Cephalic										
Adult Cephalic							1,3	Persisting of	n n Silin in Jacque	1.00
Cardiac	İ									
Transesophageal										
Transrectal				•						
Transvaginal			-			-			, , , , ,	
Transurethral										
Intravascular										
Peripheral Vascular										godenne o
Laparascopic						,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				
Musculo-skeletal Conventional							e (5.6	The second of	te ille webt in een toetka	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Musculo-skeletal Superficial							es ega i	e i soupe in	e e e e e e e e e e e e e e e e e e e	** - *** *
Other (specify)								age segretaria	eri e	

N= new indication; P= previously cleared by F	FDA; E= added under Appendix E
Additional Comments:	
Color Doppler & Amplitude Doppler only	on Sigma 330 Systems
Concurrence of CDRH,	Office of Device Evaluation (ODE)
	Sample Segum
	(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices
Prescription Use (Per 21 CFR 801.109)	510(k) Number <u>Koo 2239</u>

System: Sigma 110 / 330

Transducer: 5.0 MHz CUR

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		,				Mode of O	peration			
Clinical Application	Α	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N						
Abdominal		N	N	N						
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N						
Small organs (specify)		N	N	N				-34		ena aleman di angle essar
Neonatal Cephalic			1							
Adult Cephalic			İ					ं पानस्य	Sparke earlie	
Cardiac										
Transesophageal								77.50		***
Transrectal					- 			,		
Transvaginal								alama a jew eq.	গ্ৰহ্ম কৰা সংগ্ৰহ	Programme of the second
Transurethral		-								
Intravascular								1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		<u>a. 111 jaan 1999 ja 1</u>
Peripheral Vascular								A. J. J. S. S. S. J. S. J. S. J. S.	يوا من ياء	anger and the control of the control
Laparascopic										
Musculo-skeletal Conventional		N	N	N					1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	ANTONIO SOLIO
Muscuło-skeletal Superficial		N	N	N					The second secon	The second second
Other (specify)								5.55 (6.5)		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional

Comments:
.......Color Doppler & Amplitude Doppler only on Sigma 330 Systems

Small organs: Thyroid, Breast, Testicle

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Section B

Prescription Use (Per 21 CFR 801.109)

July 12, 2000

and Radiological Devices

System: Sigma 110 / 330

Transducer: 5.0 MHz LIN

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode of O	peration			
Clinical Application	. А	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N						
Abdominal		N	N	N						
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N						
Small organs (specify)		N	N	N					i teta jatodi	ومن والمناوي والمناوي و
Neonatal Cephalic									, con age	10.110
Adult Cephalic								- John Sa	a (as, 1 mb)4	in the second second
Cardiac										
Transesophageal										
Transrectal									1000	
Transvaginal										Terrore di Terroriale
Transurethral							247	e no ne na a propies	1747,5174.443.3	A Marie Control
Intravascular										
Peripheral Vascular									n was in the major	u
Laparascopic								6 - N. J. S.		
Musculo-skeletal Conventional		N	N	N			**		united of Magai	to proceed to
Musculo-skeletal Superficial		N	N	N				i i in an	1 (1948)	residentes y
Other (specify)			1							

N= new indication; P= previously cleared by PDA	C = added under Appendix E
Additional Comments:	
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Color Doppler & Amplitude Doppler only on	Sigma 330 Systems
Small organs: Thyroid, Breast, Testicle	olg.ma ooc oyeleme
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	(Division Sign-Off)
	Division of Reproductive, Abdominal, ENT,
	and Radiological Devices
	510(k) Number <u> </u>
Prescription Use (Per 21 CFR 801.109)	STO(K) NUMBER

Section B July 12, 2000

System: Sigma 110 / 330

Transducer: 7.5 MHz LV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application	Α	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic													
Fetal													
Abdominal		N.	N	N		N	N						
Intraoperative (specify)													
Intraoperative Neurological													
Pediatric		N	N	N		N	N	•					
Small organs (specify)		N	N	N		N	N	-10		5			
Neonatal Cephalic		N	N	N		N.	N			. ty sta			
Adult Cephalic						·		7 840)	and the space	* ** * * * * * * * * * * * * * * * * *			
Cardiac													
Transesophageal								. T - No.					
Transrectal									i de la companya de la companya de la companya de la companya de la companya de la companya de la companya de La companya de la co				
Transvaginal							3,44,9	1994	(SK	71 a 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			
Transurethral							. 5	to exception					
Intravascular								. ~					
Peripheral Vascular		N	N	N		N	N "x	suns in the system	°				
Laparascopic									***				
Musculo-skeletal Conventional		N	N	N		N	N ···	· correct	n er i sanskrig	te to experience			
Musculo-skeletal Superficial		N	N	N		N	N -	e e e e e e e e e e e e e e e e e e e	ang transporta				
Other (specify)									1.456.25.11.11.12.22.2				

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional
Comments:

......Color Doppler & Amplitude Doppler only on Sigma 330 Systems
Small organs: Thyroid, Breast, Testicle

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,

Prescription Use (Per 21 CFR 801.109)

510(k) Number K002239

and Radiological Devices

System: Sigma 110 / 330

Transducer: 7.5 MHz LVS

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode of O	peration			
Clinical Application	A	В	М	PWD	cwo	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N			
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N			
Small organs (specify)		N	N	N		- N	N	1919 1919	t to the state of	
Neonatal Cephalic		N	N	N		N	N			
Adult Cephalic								in the state of th	a and an and a second	142
Cardiac										
Transesophageal									·	
Transrectal								2 *		
Transvaginal							200	25 77 200	Company of the second	V 94-10-1
Transurethral							40	5 1 38 A N A A		100°, 12 m.
Intravascular						·			41.	
Peripheral Vascular		Ν	N	N		N	Ν .,	- 1111 - V.MASS	The section of	1, 4,555,16
Laparascopic								esta e		
Musculo-skeletal Conventional		Ν	N	N		N	N	- Nemap whee	t top or extended	· · · · · · · · · · · · · · · · · · ·
Musculo-skeletal Superficial		N	N	N		N	N	ran inga	10.170	sand of
Other (specify)								1. 100	2001-01	

Prescription Use (Per 21 CFR 801.109)

System: Sigma 110 / 330

Transducer: 7.5 MHz LVD

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic													
Fetal													
Abdominal		N	N	N		N	N						
Intraoperative (specify)									•				
Intraoperative Neurological													
Pediatric		N	N	N		N	N						
Small organs (specify)		N	N	N		N	N		uur rugareess	1			
Neonatal Cephalic		N	N	N		N	N			· · · -			
Adult Cephalic								1009	no establish				
Cardiac													
Transesophageal													
Transrectal								7	. See a see a see a see a see a see a see a see a see a see a see a see a see a see a see a see a see a see a	an affan i de			
Transvaginal								Market Control					
Transurethral								Village Street	The state of the s				
Intravascular													
Peripheral Vascular		N	N	N	<u> </u>	N	N	ar makan in inda	and the second second				
Laparascopic									,				
Musculo-skeletal Conventional		N	N	N		N	N	M (1	L. White,			
Musculo-skeletal Superficial		N	N	N		N	N	m sempeye his	a spage	and the state of			
Other (specify)						1	1	1.20					

N= new indication; P= previously cleared by 1 DA,	L- added drider Appendix E
Additional	
Comments:	

Color Doppler & Amplitude Doppler only on S	Sigma 330 Systems
Small organs: Thyroid, Breast, Testicle	
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	(Division Sign-Off)
	Division of Reproductive, Abdominal, ENT,
	and Radiological Devices
	510(k) Number <u>K002239</u>
Prescription Use (Per 21 CFR 801.109)	

System: Sigma 110 / 330

Transducer: 6.5 MHz VMC

	·					Mode of O	peration			
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic								-		
Fetal		N	N	N		N	N			
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)								. 2044	e Communicações	
Neonatal Cephalic										
Adult Cephalic							tr		1,111 PM 1845	4
Cardiac										
Transesophageal							<i>pt.</i> ,	, X- X- X- X		
Transrectal		N	N	N		N	N		1 1 1 1 1 1 1 1 1	
Transvaginal		N	N	N		N	N	To the same same	7.7.7.7.4	e
Transurethral							4.44.00	n, set war, ta	ورده در در در در در در در در در در در در در	to Segregation and
Intravascular								5		
Peripheral Vascular								in the second se	State of the following	t surestant in
Laparascopic									1	
Musculo-skeletal Conventional							1514	بعر بيد	m, e e e e e e e e e e e e e e e e e e e	an etc. Ten
Musculo-skeletal Superficial								and the second second	e e e e e e e e e e e e e e e e e e e	efekte af
Other (specify)			1					n. Number		

N= new indication; P= previously cleared by FD	A; E= added under Appendix E
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Color Doppler & Amplitude Doppler only o	n Sigma 330 Systems
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	(Division Sign-Off)
	Division of Reproductive, Abdominal, ENT,
	and Radiological Devices
	510(k) Number <u>KOO2239</u>
Prescription Use (Per 21 CFR 801.109)	

System: Sigma 110 / 330

Transducer: 6.5 MHz EV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application	Α	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetal		N	N	N	:							
Abdominal												
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric												
Small organs (specify)									.1.5.29	+4,-,4		
Neonatal Cephalic							,					
Adult Cephalic							<u> </u>	d. 75%	a superior to the st	y service y		
Cardiac												
Transesophageal												
Transrectal		N	N	N								
Transvaginal		N	N	N				1 11/4				
Transurethral								Mark to the annual transfer	g esta a jakoja at seg	into daletto in 1906		
Intravascular												
Peripheral Vascular								2 44/70	geranica in the acceptance	er i selestico e		
Laparascopic												
Musculo-skeletal Conventional								e size / a	2 - 1,10 - 1,10 M			
Musculo-skeletal Superficial							·		er - ran artaga everytis			
Other (specify)									3	<u> </u>		

ther (specify)									
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Prescription Use	(Per 21 CFR 80	1.109)		10(k) Nu	- I -	0022	239		

System: Sigma 110 / 330

Transducer: 6.5 MHz MR

						Mode of O	peration			
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)									100	
Neonatal Cephalic							-12.01-		, -44	
Adult Cephalic								· v		
Cardiac										
Transesophageal										
Transrectal		N	N	N				(6)	The end was	
Transvaginal ·									7	
Transurethral							.5%	1000	a service of the	
Intravascular								are.		
Peripheral Vascular							in the second	a to the stand		
Laparascopic								12.12.25	, , , , , , , , , , , , , , , , , , ,	
Musculo-skeletal Conventional							180			
Musculo-skeletal Superficial							11 mg 11 da 11 da 11 da 11 da 11 da 11 da 11 da 11 da 11 da 11 da 11 da 11 da 11 da 11 da 11 da 11 da 11 da 11			
Other (specify)					,			6 m - 12 m	71. TV - 44.19	

Other (specify)							no fize existin	
N= new indication; P	= previously cl	leared by FD)A; E= a	dded und	ler Appen	dix E		
Additional								
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	Concurrence	of CDRH, O	ffice of	Device E	Evaluation	(ODE)		·=
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				vision Sig		1		
			Divi and	ision of F Rådiolog	Reproducti ical Devic	ve, Abdomi ces	nal, ENT,	
	4.9		510	k) Numt	er <i>K</i>	0022	39	
Prescription Use (Pe	r 21 CFR 801.	109)					7	

System: Sigma 110 / 330

Transducer: 3.5 MHz GP

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode of O	peration			
Clinical Application	Α,	В	м	PWO	CMD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic							·			
Fetal		N	N	N	N					
Abdominal		N	N	N	N					
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)										,
Neonatal Cephalic								·	. •	
Adult Cephalic										
Cardiac		N	N	N	N					
Transesophageal										
Transrectal									िकार प्रदेश एक र	
Transvaginal										
Transurethral							1.000			
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional								5 - A		_
Musculo-skeletal Superficial										
Other (specify)]

N= new indication; P= previously cleared by f	FDA; E= added under Appendix E
Additional Comments:	
Concurrence of CDRH,	Office of Device Evaluation (ODE)
	David a. begenon
	(Division Sign=Off)
	Division of Reproductive, Abdominal, ENT,
/	and Radiological Davices
	510(k) Number K00 2239
√Prescription Use (Per 21 CFR 801.109)	STOCK) INUMOSI WAS A STATE OF

System: Sigma 110 / 330

Transducer: 3.5 MHz GPD

						Mode of O	peration			
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic							•			
Fetal		N	N	N	N					
Abdominal		N	N	N	N					
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)										
Neonatal Cephalic									W .	
Adult Cephalic									15 constant	
Cardiac	. 0.24	Z	N	N	N					7 77 7.4
Transesophageal					<u> </u>		· ·			
Transrectal								· .		
Transvaginal	7. 1048	. 176			•		## · · · · · · · · · · · · · · · · · ·			
Transurethral				e Sal			1.25 (1		in mannesses	* 1984 *1 1955
Intravascular								,		
Peripheral Vascular							24		وي يو معود ي در در در در در در در در در در در در در	
Laparascopic										
Musculo-skeleta! Conventional				*			1998 - 450		20 to t	* *·
Musculo-skeletal Superficial	-: 1ja	•		,	A. 40		e i e e e e e e e e e		en en en en en en en en en en en en en e	a the
Other (specify)									11102 11 1 1	

onventional	-					
lusculo-skeletal uperficial	٠, ٠, ٠		ودانيات داد			
Other (specify)				1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	e forsk efter spe	
N= new indication; P= previously cleared b	y FDA; E= a	dded und	er Appendi:	ĸ'Ē	<u> </u>	
Additional Comments:	***************	••••	************			
				/		
		**********	**********			
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						*
Concurrence of CDRI	H, Office of	Device E	valuation (ODE)		
		TEHER SIN	1 6 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	eym	n	
	Divi	sion ôf R	eprodu etive	, Abdomii	nal, ENT,	
		_	eal Devices	~ ~ ~)a	
√Prescription Use (Per 21 CFR 801.109)	510(k) Numb	F-ACC	122	27	

System: Sigma 110 / 330

Transducer: 3.5 MHz GL

		,				Mode of O	peration			
Clinical Application	A	В	М	PWD	cwo	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify
Ophthalmic										
Fetal		N	N	N	N					
Abdominal		N	N	N	N					
Intraoperative (specify)									-	
Intraoperative Neurological										<u> </u>
Pediatric										
Small organs (specify)									- 24	
Neonatal Cephalic										
Adult Cephalic							.54	Y	1.0	× 6.9
Cardiac		N	N	N	N					
Transesophageal										
Transrectal										
Transvaginal							44		. ''q	
Transurethral										
Intravascular							A1: 0		52.09	1,284
Peripheral Vascular										
Laparascopic								t eguntaga		
Musculo-skeletal Conventional								1,111,111	7.41-	6.7
Musculo-skeletal Superficial								1 Tu 10 10 10 10 10 10 10 10 10 10 10 10 10		
Other (specify)										* **

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N= new indication;	P= previously	cleare	d by FC)A; E= a	dded und	ler Appendi	×Ε		
Additional									
Comments:	•••••••••••	••••••	• • • • • • • • • • • • • • • • • • • •			• • • • • • • • • • • • • • • • • • • •		•••••	
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	Concurrence	of C	ORH, O	ffice of	Device E	valuation (ODE		
	,				Jain	l a.		m	
					sion Sign		1		
,				Divis	ion of Re	productive	, Abdomin	al, ENT,	
						cal Devices		7.0	
Prescription Use (P	er 21 CFR 801	1.109)		510(k	() Numbe	$r = \Delta C$	CIJ	3 Y	

System: Sigma 110 / 330

Transducer: 5.0 MHz GP

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetal		Ν	N	N.	N							
Abdominal		N	N	N	N				<u> </u>			
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric		N	N	N	N							
Small organs (specify)		N	N	N	N							
Neonatal Cephalic												
Adult Cephalic										1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
Cardiac		N	N	N	N							
Transesophageal										ļ		
Transrectal									27 s Love 1980			
Transvaginal												
Transurethral									1 Maria	7 J		
Intravascular												
Peripheral Vascular									1.110000			
Laparascopic												
Musculo-skeletal Conventional		N	N	N	N		20					
Musculo-skeletal Superficial		N	N	N	N		*3 0. 5. 1	3.				
Other (specify)						1		.,	4			

her (specify)		<u> </u>		<u> </u>				<u> </u>		
N= new indication;	P= previously	cleared	d by FC)Α; E= ε	idded un	der Appen	dix E			
Additional	,								*	
Comments:										
									••••••	
		•••••		• • • • • • • • • • • • • • • • • • • •			• • • • • • • • • • • • • • • • • • • •	••••••		••••
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	Concurrence	o of C	הפט כ	Office of	Device	Evaluatio	n (ODE)			
	Concurrenc	e or C	DKH, C	Jince O		/ /	2 1			
					Van	ind U.	Seg	mm		
				(D	ivision S	ign-Off)	r		_	
							tive, Abdo	minal, EN	Γ,	
				an	d Radiol	ogical Dev		~ ~ ~		
Prescription Use (F	er 21 CFR 80	01.109)	ı	51	0(k) Nun	nber	002	<u> </u>		
						;		/	_	

System: Sigma 110 / 330

Transducer: 5.0 MHz GL

						Mode of O	peration			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N					
Abdominal		N	N	N	N					· · · · · · · · · · · · · · · · ·
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	· N	N					
Small organs (specify)		N	N	N	N				and the second	
Neonatal Cephalic										
Adult Cephalic							 e 250 .0	*** · 4	·. (45	to the contract
Cardiac		N	N	N	N					
Transesophageal								·		
Transrectal										
Transvaginal							-			
Transurethral					·		Control of			A
Intravascular										
Peripheral Vascular							ti n njetope			
Laparascopic										
Musculo-skeletal Conventional		N	N	N	N		Market Jak		. 50 . 70	
Musculo-skeletal Superficial		N	N	N	N		94 or AN			1
Other (specify)										

				1		!	1	1
N= new indication; P=	previously cl	eared by FD	A; E= a	dded und	er Appendi	xΈ		
Additional			•					
Comments:	•••••	• • • • • • • • • • • • • • • • • • • •			••••••	•••••	*********	

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U	oncurrence o	of CDRH, Of	fice of	Device Ev	valuation (ODE)		
				Vain	la.	60.		
			(Divis	sion Sign-		sym	100	
			Divis	on of Da	OII)	, ,		
			and R	adiologic	productive, al Devices	Abdomin	al, ENT,	
Prescription Use (Per	21 CED 904 4	(00)			,			
r rescription use (Fet	21 OFK 601.1	109)	510(k) Number	KOC	シンノ	39	

System: Sigma 110 / 330

Transducer: 7.5 MHz GP

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode of O	peration			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic							-			
Fetal		N	N	N	N					
Abdominal		N	N	N	N					
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N					
Small organs (specify)		N	N	N	N				onequal onequal	The second of the second
Neonatal Cephalic		N	N	N	N					
Adult Cephalic									President	. 1.4
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral							6155.1			
Intravascular										
Peripheral Vascular		N	N	N	. N		to the second		+ + 1×2×24	
Laparascopic										
Musculo-skeletal Conventional		N	N	N	N	N. C. H			1 100	ravia.
Musculo-skeletal Superficial		N	N	N	N				ery i	e este e e
Other (specify)										

Superiiciai			1		,	
Other (specify)					es.	
N= new indication; P= previo	ously cleared by F	DA; E= added un	der Appendix	E		
Additional Comments:					••••	
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		_{jije} .				
Concur	rence of CDRH, (/ /	•	=		
		(Division Si	in a	Segar	m	
		Division of	gn-Off)	4		
		and Radiolog	Reproductive	Abdomi	nal, ENT,	

Prescription Use (Per 21 CFR 801.109)

System: Sigma 110 / 330

Transducer: 7.5 MHz GL

						Mode of O	peration			
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N	N					
Abdominal		N	N	N	N					
Intraoperative (specify)										
Intraoperative Neurological										-
Pediatric		N	N	N	N					
Small organs (specify)		N	N	N	N				e fee jagen	November 1
Neonatal Cephalic		N	N	N	N					
Adult Cephalic			1					1 100%		
Cardiac			1							
Transesophageal		,		έε						
Transrectal										
Transvaginal			1	,						
Transurethral								on many		
Intravascular										1 - **
Peripheral Vascular		N	N	N	N					. a Parka
Laparascopic										
Musculo-skeletal Conventional		N	N	N	N			Today - Today		
Musculo-skeletal Superficial		N	N	N	N			n en en	and the second	A The industrial of the second
Other (specify)										

the toposity				J		ł	1			
N= new indication;	P= pre	viously	cleare	d by F	DA; E= a	idded und	der Append	ix E	<u> </u>	
Additional										
Comments:	••••••	• • • • • • • • • • • • • • • • • • • •	•••••	•••••	•••••	• • • • • • • • • • • • • • • • • • • •	***************************************		••••••	
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	Conc	ırrence	e of Cl	DRH, O	ffice of	Device/E	valuation	(ODE)		
et.						<i></i>	and b	7. Les	10m.	
							on Sign-Of	0	mp -	
Prescription Us	e (Per	21 CF	R 80	1.109))	Divisio	n of Repro	ductive, Al	odominal, E	NT.
				,		and Ra	diological I	Devices		
						510(k)	Number/	K002	239	

System: Sigma 110 / 330

Transducer: 14 MHz PV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode of O	peration			
Clinical Application	Α	В	м	PWD	cwo	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N						
Intraoperative (specify)										
Intraoperative Neurological										V . 4147
Pediatric		N	N	N						
Small organs (specify)		N	N	N					- 71. ON	. 14 1, 1, 1, 1
Neonatal Cephalic		N	N	N						٠.
Adult Cephalic									9 - 94	7 29:
Cardiac										
Transesophageal										
Transrectal								Yes.		
Transvaginal										
Transurethral								V-0,858	alband a construction	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1
Intravascular										
Peripheral Vascular		N	N	N				-1'4'		V
Laparascopic						-				
Musculo-skeletal Conventional		N	N	N	101.00			. 454	- contain	
Musculo-skeletal Superficial		N	N	N	1412.41			42		
Other (specify)									. 29	

ther (specify)			l			1		1		
N= new indicati	on; P= pre	viously	cleared	by FE	DA; E= a	added un	der Appe	endix E		
Additional										
Comments:				•••••		• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •			
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	Conc	urrence	e of CC	ORH, C	(Div	am Islon Sig		Leg	-	ENT.
					DIM	SIOH OL N	rebroanci	ive, Au	Journaldi, L	21N 19

Section B

Prescription Use (Per 21 CFR 801.109)

July 12, 2000

and Radiological Devices

510(k) Number.

System: Sigma 110 / 330

Transducer: 2 MHz TCD

						Mode of O	peration			
Clinical Application	А	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										······································
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										. 7
Pediatric								******		
Small organs (specify)									1/1/4	
Neonatal Cephalic										
Adult Cephalic				N	•				1000	F 10.5
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral							. 7,4	a to the sea	1 (1.1.2)	
Intravascular										
Peripheral Vascular							279	.,		
Laparascopic										
Musculo-skeletal Conventional							âd	- W., 9		
Musculo-skeletal Superficial								. **	A. H. J.	
Other (specify)										

Superficial								El Company	
Other (specify)									
N= new indication; P	= previously	cleare	d by FC)A; E= a	dded und	ler Appendi	хE		
Additional Comments:					······································	••••••		••••••	
••••••	••••••	••••••	••••••••			•••••••	***********	****************	***********
••••••	•••••	••••••				• • • • • • • • • • • • • • • • • • • •	••••••	•••••••••••••••••••••••••••••••••••••••	••••••
		•••••				•••••••	•••••••	•••••••	••••••
	•••••	••••••				••••••	•••••	•••••••	•••••••
	Concurrence	of C	DRH, O	ffice of	Device E	valuation	(ODE)		
				Divis	sion Sign sion of Re Radiologic	Off) eproductive	Abdomi	inal, ENT,	
Prescription Use (Pe	er 21 CFR 801	1.109)		510(1	x) Numbe	r_Ko	222	39	

System: Sigma 110 / 330

Section B

Transducer: 2 MHz PEN

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

·						Mode of O	peration			
Clinical Application	Α	В	м	PWD	cwo	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal	"									
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)									× 79	
Neonatal Cephalic							-4			-
Adult Cephalic									- ">1	
Cardiac				N	N					
Transesophageal										
Transrectal									,	
Transvaginal										
Transurethral			1				1		1. 1847	1.00
Intravascular										
Peripheral Vascular										
Laparascopic										
Musculo-skeletal Conventional									11 - 140 A. J. \$745 A	1 1 1 1 1 1 1 2 2
Musculo-skeletal Superficial						. 1249		. en	es established	
Other (specify)										

Other (specify)										
N= new indication	n; P= pre	viously	cleare	d by FC)A; E= a	dded und	ler Appendi	×Ε		
Additional Comments:							••••			
·			•••••							
•••••••										
•••••			•••••	•••••	••••••			• • • • • • • • • • • • • • • • • • • •		
						·····			••••••	· · · · · · · · · · · · · · · · · · ·
<u></u>	Conc	urrence	e of C	 DRH, C		/ /	Evaluation (`. ·		
Prescription Use	(Per 21 (CFR 80	1.109)		(Div Divi and	ision Sigr sion of Re Radiologi	n-Off) eproductive cal Devices er K C	4 , Abdomir		

July 12, 2000

System: Sigma 110 / 330

Transducer: 4 MHz PEN

Clinical Application						Mode of O	peration			
	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										*****
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organs (specify)									- 51	- 21
Neonatal Cephalic										
Adult Cephalic							777	19		
Cardiac								/		
Transesophageal									1.1	<u> </u>
Transrectal										*.***.
Transvaginal							- Line			· · · · · · · · · · · · · · · · · · ·
Transurethral		-						1.3		
Intravascular										
Peripheral Vascular				N	N		er i			
Laparascopic										
Musculo-skeletal Conventional							e ta e			
Musculo-skeletal Superficial							. 44.3			
Other (specify)										

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Concurrence of CDRH,	(Division Sign-Off)
Concurrence of CDRH,	(Division Sign-Off) Division of Reproductive, Abdominal, ENT,
Concurrence of CDRH,	(Division Sign-Off)

System: Sigma 110 / 330

Section B

Transducer: 8 MHz PEN

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode of O	peration			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										· · · · · · · · · · · · · · · · · · ·
Small organs (specify)									:	
Neonatal Cephalic										
Adult Cephalic						<u> </u>			1	
Cardiac				42	u					
Transesophageal									:	
Transrectal										
Transvaginal										
Transurethral	1								10	
Intravascular										
Peripheral Vascular				N	И		- 54.2		a carrier de la carre	. 841.
Laparascopic										
Musculo-skeletal Conventional							· · · · · · · · · · · · · · · · · · ·		Of Sues	
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FD	A; E= added under Appendix E
Additional	
Comments:	

	•••••

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	Land de kessen
/	(Division Sign-Off)
	Division of Reproductive, Abdominal, ENT,
Prescription Use (Per 21 CFR 801.109)	and Radiological Devices
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	510(k) Number <u>NOOLAS</u>

July 12, 2000